K002134

AUG 7 2000

510(k) SUMMARY
(As required by 21 C.F.R. §807.92)

(1) Name of submittor: Carol A. Adiletto, M.S.
Director of Clinical Affairs

Address of submittor: Selfcare, Inc.
200 Prospect Street
Waltham, MA 02154

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Date the summary was prepared: July 10, 2000

(2) Device Name: ONE TOUCH® Ultra™ Blood Glucose Monitoring System and is intended for home use.

Proprietary Name	Classification	ProCode	Description	Common Name
▪ ONE TOUCH® Ultra™ Blood Glucose Meter and ONE TOUCH® Ultra™ Test Strips	862.1345 Class II	75 CGA	Glucose Monitor	Glucose meter & test strips
▪ ONE TOUCH® Ultra™ Control Solution	862.1660 Class I	75 JJX	Single analyte control	Control solution
▪ Penlet Plus or ONE TOUCH® Ultra™ Soft Adjustable Depth Lancing Device	878.4800 Class I	79 FMK	Lancet, blood	Lancets

(3) Identification of the legally marketed device for determination of substantial equivalence: The modified device is substantially equivalent to the previously cleared Selfcare, Inc. FastTake Compact Blood Glucose Monitoring System, marketed pursuant to K001427.

(4) Description of changes: The modification includes reduction in test time, reduction in sample volume, a widening of the operating temperature and a low sample fill rejection mechanism.

(5) Statement of intended use: The modified device has the same intended use as the legally marketed predicate device. It is used for the quantitative measurement of glucose in fresh capillary whole blood. The ONE TOUCH® Ultra™ Blood Glucose Monitoring System is intended for use outside the body (in vitro diagnostic use) by diabetics at home as an aid to monitor the effectiveness of diabetes control.

(6) The technological characteristics of the device in comparison to the predicate: The modified device has the same technological characteristics as the legally marketed predicate device.

(7) Summary of performance data

Nonclinical	Verification, validation and testing activities were conducted to establish the performance, functionality and reliability characteristics of the modified device with respect to the predicate. Testing involved verification of software requirement specifications, product requirement specifications and user interface requirement specifications from risk analysis. Pass/Fail criteria were based on the specification cleared for the predicate device and results showed substantial equivalence.
Clinical	Clinical performance evaluations using the ONE TOUCH® Ultra™ Blood Glucose Monitoring System components were conducted for the purpose of validating the consumer use, user and professional accuracy. Test results showed substantial equivalence. No adverse events occurred during the studies. The results demonstrate that the ONE TOUCH® Ultra™ Blood Glucose Monitoring System meets all reliability requirements and performance claims.
Conclusion	The conclusion drawn from the nonclinical and clinical tests is that the modified device is as safe, as effective, and performs as well as the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 7 2000

Ms. Carol A. Adiletto, M.S.
Director of Clinical Affairs
Selfcare, Inc.
200 Prospect Street
Waltham, Massachusetts 02453

Re: K002134
Trade Name: Lifescan ONE TOUCH® Ultra™ Blood Glucose Monitoring System
Regulatory Class: II
Product Code: CGA
Dated: July 14, 2000
Received: July 14, 2000

Dear Ms. Adiletto:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 3 Labeling and "Indications for Use" Statement

ODE INDICATIONS STATEMENT

Indications for Use Statement

510(k) Number: K002134

Device Name: Lifescan ONE TOUCH® Ultra™ Blood Glucose Monitoring System

Indications for Use:

The ONE TOUCH® Ultra™ Blood Glucose Monitoring System ~~is intended to be~~ used for the quantitative measurement of glucose in fresh capillary whole blood. The ONE TOUCH® Ultra™ System is intended for use outside the body (*in vitro* diagnostic use) by diabetics at home as an aid to monitor the effectiveness of diabetes control.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K002134

Prescription Use _ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)